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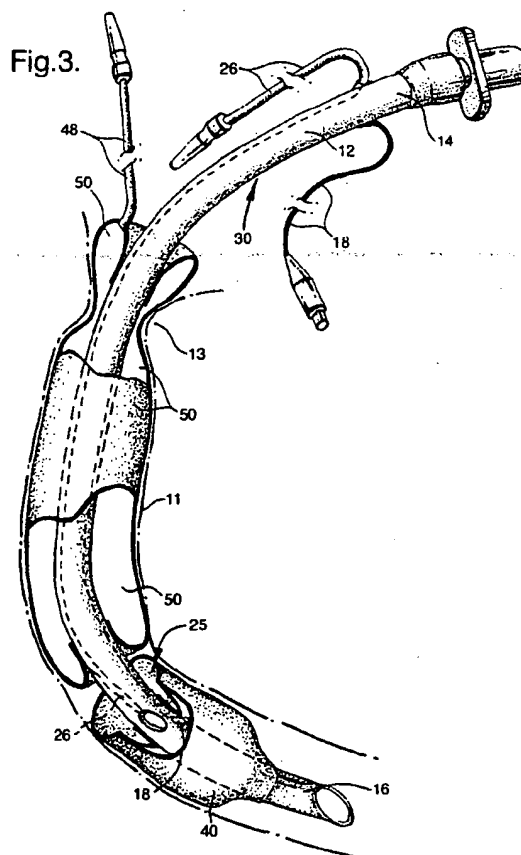
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(54) Tracheal tube devices

(57) An endotracheal tube (30) has an inflatable bag (40) towards its patient end for sealing with the inside of the trachea (11). Additionally, the tube (30) has a second, longer bag (50) separately inflatable to a lower pressure than the first bag (40) and such as to extend along the tube (30) from the first bag (40) to and through the vocal chords and larynx (13) and occupy the space between the first bag and the vocal chords (13). The inflated second bag (50) can thus reduce passage of secretions and minimises the space available for them. A suction line (26) extends along the tube (30), opening at a location (27) between, or at the interface between the two bags (40) and (50) so that any body secretions that do pass the second bag can be removed.



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Description

[0001] This invention relates to tracheal tube devices of the kind for insertion into the trachea, the device comprising a main tube encompassed towards its distal end by an inflatable bag and, extending to the interior of the bag, an inflation line by which the bag can be inflated. Generally, the inflatable bag is a cuff or a balloon.

[0002] A common feature of tracheal tube devices of this kind, such as endotracheal or tracheostomy tubes, is that bodily secretions, mucous, or other unwanted fluids can collect in the cusp between the inner surface of the body conduit and the ovate upstream surface of the inflated cuff or balloon. These bodily secretions often pass progressively between the inner surface of the trachea and the outer surface of the cuff or balloon - even though these surfaces are supposed to be in mutually sealing contact. These bodily secretions can pass from the trachea and enter the bronchi, potentially to cause lung infections. This passage of unwanted fluids past the inflated bag of the tracheal tube device, is thought to be due to the patient's breathing cycle producing fluctuating inhalation/exhalation pressures on the downstream ovate surface of the inflated bag and causing the latter and/or the tracheal conduit to act somewhat in the manner of a peristaltic pump.

[0003] One proposed solution to this problem is to provide the tube device, not only with an inflation line to the distal bag but also with a suction line opening to a region above the bag. In practice however, due to the finite axial length accommodated by the tape or other fastening means required to attach the bag sealingly to the main tube of the structure, the opening from the suction line is disposed too far above the upstream ovate surface of the bag to ensure removal by suction of all the unwanted fluids collecting in that region. Even where the collar of the bag is everted, in the manner described in GB-2250440, suction may not ensure complete removal of all secretions.

[0004] It is thus clearly desirable to provide an improved tracheal tube device.

[0005] According to the present invention there is provided a tracheal tube device for insertion into the trachea, the device comprising:

a main tube encompassed towards its distal end by a first inflatable bag;

an inflation line extending to the interior of the bag by which the bag can be inflated; and

a second bag to encompass the main tube; characterised in that

the device includes a second inflation line by which the second bag can be inflated separately from the first bag,

and in that

the second inflatable bag is dimensioned and arranged in use to occupy the space from the first inflatable bag - i.e. from contact with or close proxim-

ity to the first inflatable bag - to at least the patient's vocal chords.

[0006] Preferably, the second bag extends through the vocal chords. The second bag may be about three times the length of the first bag. The second bag is preferably inflated in use to a lower pressure than the first bag, such as between about 2 and 5 cm water. The device may include a suction line extending from the proximal end of the device and opening on the main tube at a location between the first and second bags. The first bag may have an upper surface shaped to form a receptacle for the collection of fluids. The second bag may be a cuff attached at its ends with the main tube or it may be a balloon that encompasses the wall of the main tube, in which case, the second bag may be slidable along the main tube. Advantageously, the lower end of the second bag, when inflated, nests within the receptacle provided by the upper surface of the first bag, when inflated.

[0007] According to another aspect of this invention there is provided a method of intubation into the trachea of an animal or human patient a tracheal tube device according to any preceding Claim, characterised by the steps of:

inserting the main tube and first inflatable bag through the larynx into the trachea to dispose the first bag in spaced relation to the larynx, inflating the first bag via the first inflation line, providing the second inflatable bag between the first bag and the larynx such that, when inflated, the second bag may contact or closely approach the first bag, and inflating the second bag to be in contact with or closely approach the first bag and occupy the space between the first bag and the larynx, preferably to extend through the larynx.

[0008] Advantageously, the first bag is inflated to a first pressure, and the second bag is inflated to a second pressure lower than the first pressure.

[0009] By way of example, embodiments of this invention will now be described with reference to the accompanying drawings of which:

Figure 1 is a schematic longitudinal section of an endotracheal tube according to one embodiment of this invention;

Figure 2 is a partly cut-away generalised view of the embodiment of Figure 1; and

Figure 3 is a partly cut-away generalised view of an endotracheal tube according to a second embodiment of this invention.

[0010] The illustrated endotracheal tube device 10 of Figs 1 and 2 is a tubular structure for insertion into a human or animal trachea 11 via the mouth or nose. The

device 10 incorporates a substantially conventional endotracheal tube which comprises a main tube 12 with an axial bore, the tube having a proximal or machine end 14 and a distal or patient end 16 with an inflatable bag 20 encompassing the main tube adjacent the distal end 16. The device also has a second bag 50 to be described in detail below.

[0011] An inflation line 18 leads to the interior of the bag 20 to enable it to be inflated with air to a generally ovate-shape. The inflation line 18 is attached or integrally moulded with the wall of main tube 12 for the majority of its length such as to be internally (or externally) bonded to, or extruded integrally with, the wall of main tube 12. The proximal end of the inflation line 18 is provided with a spring-loaded valve 19 (Fig 2) that is normally closed but is opened by insertion of a syringe (not shown) that is used to inflate the bag 20.

[0012] A suction line 26 is attached or integrally moulded with the wall of main tube 12 for the majority of its length such as to be externally (or internally) bonded to, or extruded integrally with, the wall of main tube 12. This suction line 26 extends to adjacent the top surface of bag 20 where it terminates in an orifice 27 that opens on the exterior surface of the tube 12, so that unwanted fluids that may collect above the bag 20 can be removed by suction.

[0013] The bag 20 may be provided by a cuff adhered at its ends to the exterior surface of main tube 12 so that the bag is defined by the cuff material and the main tube's exterior surface between the cuffs ends.

[0014] Alternatively, the bag 20 may be provided by a balloon of generally toroidal extent encompassing the main tube 12 and having the balloon's radially inner surface adhered to the exterior surface of the main tube 12.

[0015] As stated above, the endotracheal tube device 10 of this embodiment also comprises a second bag 50. This is located between the first inflatable bag 20 and the proximal end 14 of the main tube 12, the bag 50 being separately inflatable via a second inflation line 48 and such that the two bags 20, 50 (when inflated) are in contact with or very closely approach one another. The second bag 50 is substantially longer than the first, distal bag 20, typically being about three times its length. The length of the second bag 50 is chosen so that it occupies substantially all of the space between the first bag 20 and the vocal chords 13, and preferably extends through and above the vocal chords 13 by a short distance when the patient end 16 of the tube is correctly located, just above the patient's carina.

[0016] In use, following insertion of the endotracheal tube 10 into the patient's trachea, the first bag 20 - which is located spaced from the patient's vocal chords 13 - is inflated to provide a seal against the trachea 11, and the second bag 50 is then inflated so as to occupy all or at least the majority of the space or volume between the inflated first bag 20 and the larynx, or vocal chords 13.

[0017] In this way, the bag 50 minimises the trachea volume available above the bag 20 in which unwanted

fluids can collect. It thus prevents or minimises the quantity of such unwanted fluids that can exist above the bag 20 and that could travel past this bag 20 into the patient's lungs.

5 [0018] When the tube device 10 is to be extubated from the patient, the bag 50 is deflated first and, before deflating the lower bag 20, any minimal unwanted fluids collecting above bag 20 can (continue to) be removed via suction line 26.

10 [0019] The embodiment of Fig 3 provides an endotracheal tube device 30 for insertion, via the nose or mouth, into a human or animal trachea 11. The endotracheal tube device 30 is similar to that of Figs 1 and 2 except that its main tube 12 is encompassed at its distal end 16 by an inflatable bag 40 of different shape from that of the bag 20 in Figs 1 and 2. Instead of being a conventional, wholly ovate bag as shown in Figs 1 and 2, the bag 40 of Fig 3 has a shape to form (when inflated) a receptacle-like upper surface.

20 [0020] The bag 40 is shaped and/or attached to the outer wall surface of main tube 12, e.g. by tapes, adhesive, welding or the like, such that part of the inflated bag's exterior surface forms a receptacle 25 that encompasses the main tube 12 and defines therewith a space for the collection of unwanted fluids. This space is akin to a cup-shaped recess or depression formed inwardly of the body of the inflated bag at its end facing the tube's proximal end - as though that end's surface had been depressed inwards of the body of the inflated bag.

30 [0021] Depending on the size and shape of the bag 40, it is envisaged that the height of that bag's outer surface - which, when inflated, is in sealing contact with the trachea surface 11 - may be approximately 2cm to 6cm, whereas the height of that bag's inner surface in contact with the exterior surface of the main tube 12 may be approximately 0.5cm to 1.5cm where the bag is a cuff, or substantially more where the bag is a balloon. However, in either case, the depth of the receptacle 25 formed by (and between) the inflated bag's exterior surface and the main tube 12 (i.e. the distance between its mouth and its bottom) may, for example, be 2 to 4cm.

35 [0022] In use, the endotracheal tube device 30 is inserted into the patient's trachea to locate bag 40 spaced from the patient's larynx 13. Following insertion the bag 40 is inflated to provide a seal against the trachea 11, and the second bag 50 of device 30 is then inflated so as to extend from the inflated first bag 40 - into the receptacle 25 of which the lower end of second bag 50 nestingly projects - and occupy the majority of the space or volume between the first inflatable bag 40 and the larynx, or vocal chords 13. In this way, the bag 50 minimises the trachea volume available above bag 40 in which unwanted fluids can collect. It thus prevents or minimises the quantity of such unwanted fluids that can exist above bag 40 and that could travel past the bag 40 into the patient's lungs.

55 [0023] It will be appreciated that with either of the embodiments of Figs 1 to 3, the dimensions of the bag 50

are preferably such that bag 50 encompasses upper regions of the main tube 12 and extends past the vocal chords of the human or animal patient. To avoid damage to the vocal chords and/or undue patient discomfort, the second bag 50 is inflated to a pressure substantially less than that of the lower bag 20 or 40. For example, the bag 20 or 40 may be inflated to a pressure of water of approximately 15cm, whereas the second bag 50 may be inflated to a pressure of water of approximately only 2cm to 5cm.

[0024] The bag 50 may be either a cuff or a balloon that is permanently attached to the main tube 12. Alternatively, the bag 50 may be a separate balloon that, either after or prior to being fully inflated, is slid down the main tube 12 from the main tube's proximal end 14 after, the main tube is in position in the trachea with the first bag 20 or 40, is then appropriately fully inflated.

[0025] Although the above-described and illustrated embodiments of this invention have been endotracheal tubes, the present invention is considered applicable also to other tracheal devices, such as tracheostomy tubes. Furthermore it will be appreciated that other modifications and embodiments of the invention, which will be readily apparent to those skilled in this art, are to be deemed within the ambit and scope of the invention, and the particular embodiments hereinbefore described may be varied in construction and detail, e.g. interchanging (where appropriate or desired) different features of each, without departing from the scope of the patent monopoly hereby sought.

Claims

1. A tracheal tube device (10, 30) for insertion into the trachea (11), the device comprising:
 - a main tube (12) encompassed towards its distal end (16) by a first inflatable bag (20, 40);
 - an inflation line (18) extending to the interior of the bag (20, 40) by which the bag can be inflated, and
 - a second bag (50) to encompass the main tube (12) **characterised in that**
 - the device includes a second inflation line (48) by which the second bag (50) can be inflated separately from the first bag (20, 40), and
 - in that**
 - the second inflatable bag (50) is dimensioned and arranged in use to occupy the space from the first inflatable bag (20, 40) to at least the patient's vocal chords (13).
2. A device according to Claim 1, characterised in that the second bag (50) is to extend in use through the vocal chords (13).
3. A device according to Claim 1 or 2, characterised

in that the second bag (50) is about three times the length of the first bag (20, 40).

4. A device according to any one of the preceding claims, characterised in that the second bag (50) is to be in use inflated to a lower pressure than the first bag (20, 40).
5. A device according to Claim 4, characterised in that the second bag (50) is to be in use inflated to a pressure of between about 2 and 5 cm water.
6. A device according to any one of the preceding claims, characterised in that the device includes a suction line (18) extending from the proximal end of the device and opening on the main tube (12) at a location (27) between the first and second bags (20, 40 and 50).
7. A device according to any one of the preceding claims, characterised in that the first bag (40) has an upper surface shaped to form a receptacle (25) for the collection of fluids.
8. A device according to any one of claims 1 to 7, characterised in that the second bag (50) is a cuff attached at its ends with the main tube (12).
9. A device according to any one of Claims 1 to 7, characterised in that the second bag is a balloon that encompasses the wall of the main tube.
10. A device according to Claim 9, characterised in that the second bag (50) is slidable along the main tube (12).
11. A method of intubation into the trachea of an animal or human patient a tracheal tube device according to any preceding Claim, characterised by the steps of:
 - inserting the main tube (12) and first inflatable bag (20, 40) through the larynx into the trachea to dispose the first bag (20, 40) in spaced relation to the larynx,
 - inflating the first bag (20, 40) via the first inflation line (18),
 - providing the second inflatable bag (50) between the first bag (20, 40) and the larynx such that, when inflated, the second bag (50) may contact or closely approach the first bag (20, 40), and
 - inflating the second bag (50) to be in contact with or closely approach the first bag (20, 40) and occupy the space between the first bag (20, 40) and the larynx.
12. A method according to Claim 11 characterised in

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that the second inflatable bag (50) is positioned to extend through the larynx.

13. A method according to Claim 11 or Claim 12, characterised in that the first bag (20,40) is inflated to a first pressure, and in that the second bag (50) is inflated to a second pressure lower than the first pressure.

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Fig.3.

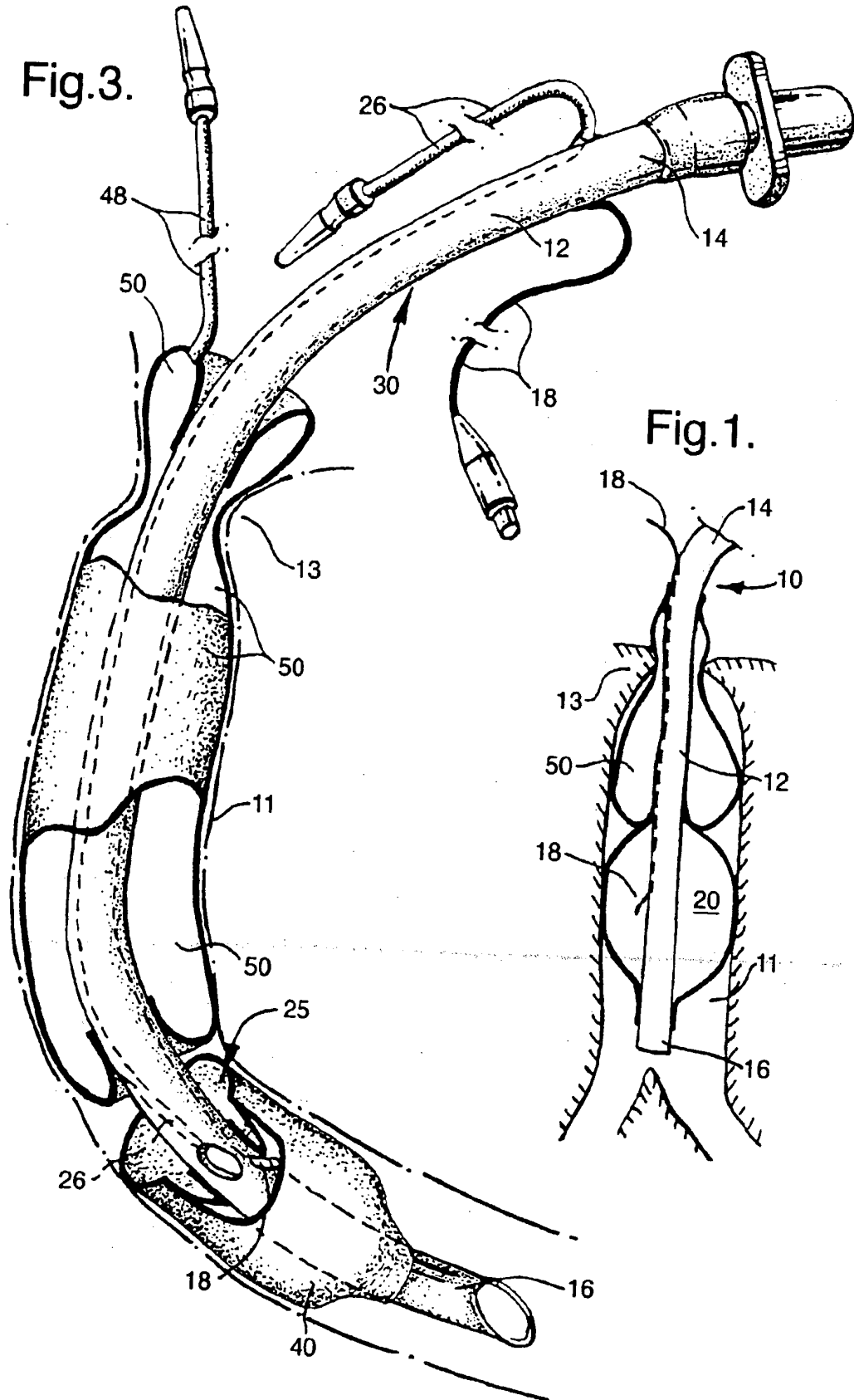
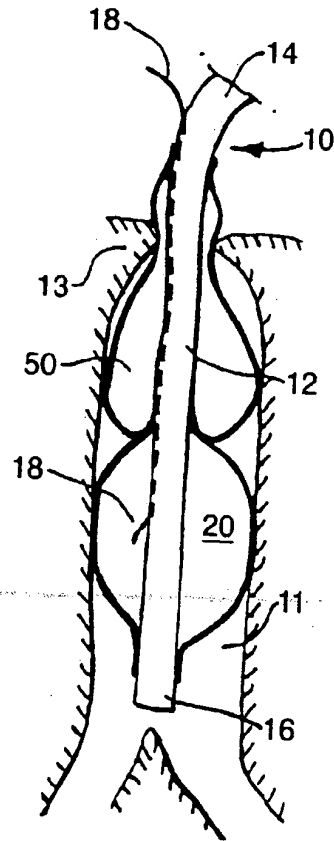


Fig.1.



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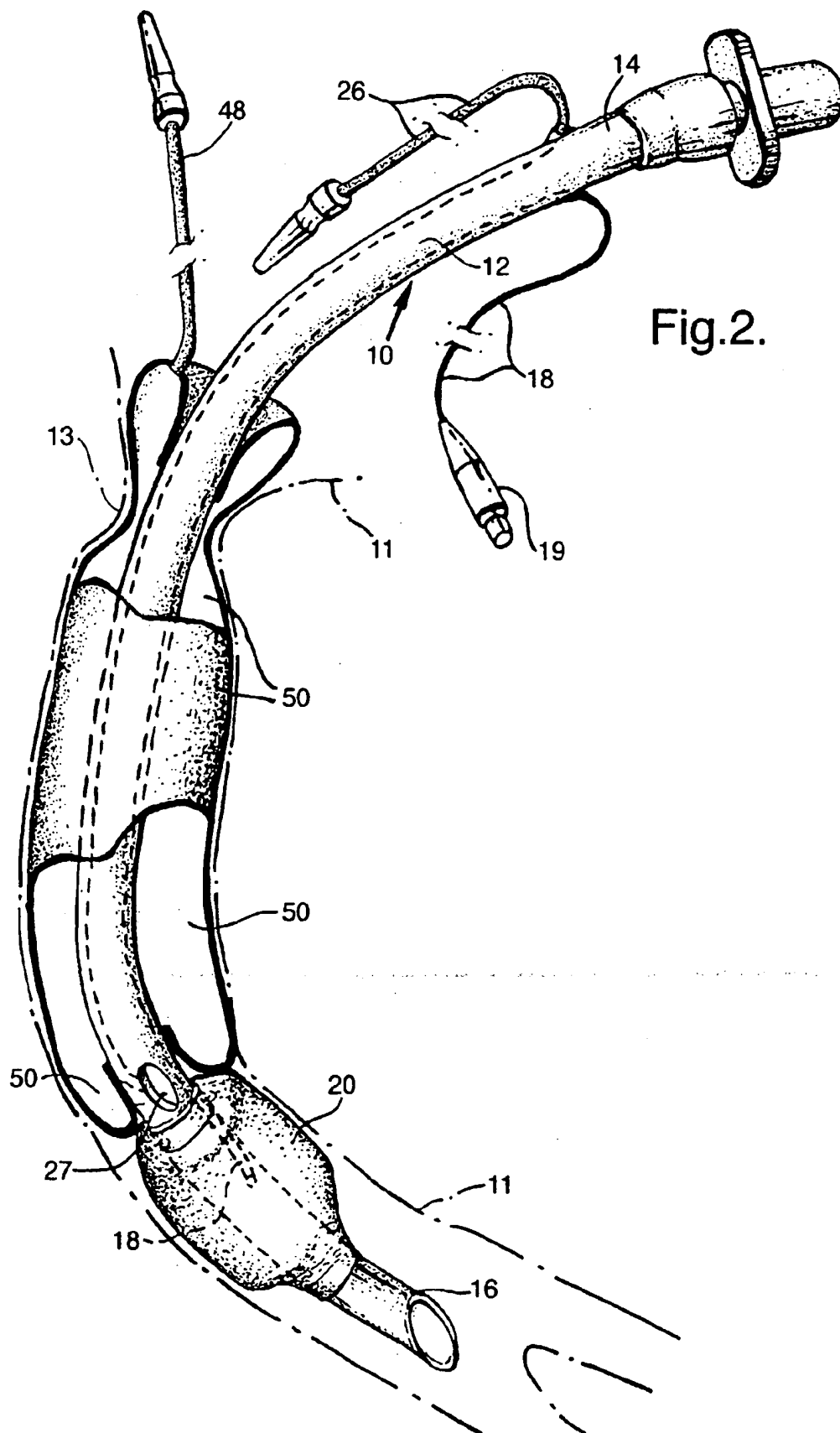


Fig.2.



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which under Rule 45 of the European Patent Convention
shall be considered, for the purposes of subsequent
proceedings, as the European search report

Application number

DOCUMENTS CONSIDERED TO BE RELEVANT			EP 98307007.9
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl. 6)
Y	US 4091816 A (ELAM, J.O.) 30 May 1978 (30.05.78), fig. 5,6,7, abstract, column 2, lines 59-64, column 3, lines 52-68.	1-4,8, 9	A 61 M 16/04
A	--	5,6	
Y	US 5033466 A (WEYMULLER, E., JR.) 23 July 1991 (23.07.91), the whole document, especially fig. 1-3, abstract, column 2, lines 14,15, column 3, lines 32- 40, column 4, line 46 - column 5, line 40.	1-4,8, 9	
A	--	5	
Y	US 4341210 A (ELAM, J.O.) 27 July 1982 (27.07.82), the whole document, especially fig. 1-6, column	1-3,8, 9	TECHNICAL FIELDS SEARCHED (Int. Cl. 6)
			A 61 M
INCOMPLETE SEARCH			
<p>The Search Division considers that the present European patent application does not comply with the provisions of the European Patent Convention to such an extent that it is not possible to carry out a meaningful search into the state of the art on the basis of some of the claims.</p> <p>Claims searched completely: 1-10</p> <p>Claims searched incompletely:</p> <p>Claims not searched: 11-13 according to Art. 52(4) and methods for treatment of the human or animal body by ... therapy with regard to the wording of claim 11: "Method of intubation into the trachea.... by inserting the main tube through the larynx ..." etc..</p> <p>Reason for the limitation of the search:</p>			
Place of search VIENNA	Date of completion of the search 16-12-1998	Examiner LUDWIG	
CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background D : non-written disclosure P : intermediate document T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document			

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Application Number

EP 98307007.9

DOCUMENTS CONSIDERED TO BE RELEVANT			CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	
A	4, line 46 - column 5, line 51, column 6, lines 19-24.	6	
Y	<p>GB 693510 A</p> <p>(BLEASE, J.H.) 01 July 1953 (01.07.53),</p> <p>fig. 3, page 1, lines 49-57, page 1, line 93 - page 2, line 7.</p>	1-3, 8, 9	
A	<p>EP 0490852 A1</p> <p>(MEDICAL PRODUCTS OCTAGON AB) 17 June 1992 (17.06.92),</p> <p>fig. 1.2, column 3, line 18 column 4, line 15.</p>	1-3	TECHNICAL FIELDS SEARCHED (Int.Cl.6)
A, D	<p>GB 2250440 A</p> <p>(SMITHS IND. PUBL. LTD. COMP.) 10 June 1992 (10.06.92),</p> <p>the whole document, especially fig. 1.2, abstract.</p>	6, 7	

EPO FORM 1503 (1.1.92) (P.O.C.10)

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ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 98307007.9

This annex lists the patent family members relating to the patent documents cited in the above-mentioned search report. The members are as contained in the EPIDUS INPAUC file on 21.12.1998. The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US A 4091816	30-05-78	CA A1 1109750 GB A 1557021	29-09-81 05-12-79
US A 5033466	23-07-91	none	
US A 4341210	27-07-82	US A 4235239	25-11-80
GB A 693510		none	
EP A1 490852	17-06-92	DE CO 69118844 DE T2 69118844 DE B1 490852 DE AO 9003934 DE A 9003934 DE B 467140 DE C 467140	23-05-96 05-09-96 17-04-96 10-12-90 01-06-92 01-06-92 24-09-92
GB A1 2250440	10-06-92	AU A1 87925/91 AU B2 647206 CA AA 2056015 DE CO 69102982 DE T2 69102982 DK T3 489507 EP A1 489507 EP B1 489507 ES T3 2057782 GB AO 5026405 GB AO 9124045 GB B2 2250440 IE B 64695 IL AO 100025 IL A1 100025 JP A2 4272766 US A 5201310	11-06-92 17-07-94 06-06-92 29-08-94 27-10-94 12-09-94 10-06-92 20-07-94 16-10-94 23-01-91 02-01-92 15-10-94 26-08-95 18-08-92 31-12-95 29-06-92 13-04-93

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